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Family Practice

May 17, 1999

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20857-0003

Re: Docket No. 98N-1265

To the Federal Drug Administration,

As a physician I am submitting this letter to express my concern and opposition to the Memorandum of Understanding (MOU) as published by the FDA on January 21, 1999.

In its present form, the MOU, as well as the Compounding Section 503A of the Modernization Act, markedly restricts my rights as a physician as well as patients, to obtain healthcare products from providers of their choice. In addition the rights of compounding pharmacists to serve the medical needs of the public are being violated. Pharmacists frequently inform patients and physicians of alternative drugs that might be better suited to treating a particular problem or symptom. This time-honored patient-physician-pharmacist relationship is jeopardized because the MOU labels this common professional practice solicitation, if the alternative is a compounded drug. In reality, the MOU places a gag order on pharmacists who specialize in compounded drugs. The MOU clearly discriminates against compounded prescriptions by severely limiting the interstate distribution of these medications considering that there is no such limitation for noncompounded prescriptions. As a physician, there should be no restrictions to the delivery of a compounded medication that I prescribe, regardless of where the patient may live or travel. In all fairness and for freedom of choice, the MOU must be amended!

The FDA which purports to have consumer safety as its mission is overstepping its boundaries in this circumstance since compounded prescriptions are safe and beneficial. Clearly this is not a safety issue. The FDA, a governmental agency, which represents the people has the responsibility to be accountable to the people. Therefore, I strongly urge that the MOU be amended.

Sincerely,

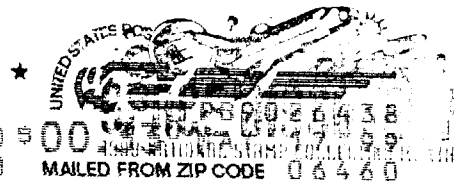
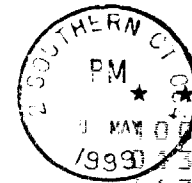


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98N-1265

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